

REMARKS/ARGUMENTS

Claims 15-32 are pending in this application. Claims 1-14 have previously been canceled. Claim 15 has been amended. Claims 29-32 are new.

The Section 101 Rejection

All claims were rejected as being directed to non-statutory subject matter because neither the referred to microprocessor nor the random generator are positively recited.

Claim 15 has been amended, and it now positively recites both the microprocessor and the random generator. In view thereof, the Section 101 rejection of claims 15-19 is requested.

Method claims 22-28 were apparently also rejected under Section 101, although the Office Action limits its comments to claim 15.

Applicant submits that *In re Bilski*, 88 USPQ2d 1385 (Fed. Cir. 2008), is not applicable to method claims 22-30 because the claims are for a process that involves a physical transformation of physical objects or substances, namely the stimulation of a muscle or a group of muscles of a person.

In view thereof, applicant also requests the retraction of the Section 101 rejection of method claims 22-30.

Substantively, claims 15, 17, 20-22, 24 and 27-28 were rejected for anticipation or, in the alternative, for obviousness over Krikorian (4,541,417), and claims 16, 18, 19, 23, 25 and 26 were rejected for obviousness over Krikorian.

The Section 102 Rejection

The basis of the present invention as defined by the claims, and in particular by independent claims 15 and 22 lies in the recognition that if a muscle is continuously stimulated with electrical stimulation in accordance with a fixed pattern, then the muscle can become so accustomed to the stimulation that it no longer reacts in the appropriate manner. This is akin to a

situation in which a person is exposed to a continuous sound over a longer period of time and then effectively no longer hears this sound because it is filtered out by his brain. To prevent the muscle from becoming accustomed to the electrical stimulation, independent claims 15 and 22 require that at least some of the listed parameters are intentionally varied in accordance with a predetermined pattern or randomly within pre-specified limits in the course of a long treatment to prevent the muscle affected by the electrical stimulation and the body's response to the muscle contraction from getting used to the fixed pattern of electrical stimulation.

This is not disclosed or suggested in the prior art, as the following demonstrates.

The Office Action took the position that the electrotherapy apparatus of Krikorian is adapted to vary at least one of the amplitude, the pulse repetition frequency, the duration of the pulse and the offset in accordance with an adjustment by an operator. It concludes that the apparatus of Krikorian is therefore suitable to vary these parameters in accordance with a predetermined pattern within pre-specified limits in the course of a treatment extending over many heart cycles.

Applicant acknowledges that the apparatus of Krikorian enables an operator to vary such parameters as the amplitude, the pulse repetition frequency and the duration of the offset if he chooses to do so for one purpose or another. In Krikorian the operator must choose specific values for the listed parameters which are then retained for the treatment to which the patient is subjected. In accordance with Krikorian, the values might be changed during treatment if the parameters initially chosen did not appear to be ideal for the treatment of the patient in question.

There is not even a recognition in Krikorian that muscles can be prevented from becoming tired by continuous stimulation. This is found only in the present application (page 3, paragraph 4 of the application as originally filed), which refers to sequencing, i.e. to providing, say, four electrodes which are positioned in proximity to muscles of an associated group of muscles with electrical stimulation being fed first to one electrode and then to the next electrode and then to the next and so on, so that each electrode is energized in sequence. This gives each

affected muscle a rest period of three heartbeats (if four electrodes are provided and only one is stimulated for each beat of the heart), which, as an additional benefit, helps counteract the muscles becoming tired. It is also stated in paragraphs 2 and 3 on page 2 of the present application that random energization of the electrodes with successive pulse trains or groups of pulse trains is also feasible.

These distinguishing features are explicitly set forth in independent claim 15, which recites in relevant parts that the electrotherapy apparatus is adapted to vary at least one of the cited parameters “*in accordance with a predetermined pattern stored in the associated microprocessor or the random generator within pre-specified limits in the course of a treatment extending over many heart cycles*”.

Independent method claim 22 is similarly limited and requires in relevant parts “*wherein at least one of said amplitude, said pulse repetition frequency, said duration and said offset is varied in accordance with a predetermined pattern, or randomly, within pre-specified limits in the course of a treatment extending over many heart cycles*”.

New independent claims 29 and 30 depend from claim 22, and new dependent claims 31 and 32 depend from claim 15. Claims 29 and 31 require in relevant parts that “*the treatment lasts for more than 15 minutes*” (claim 31; claim 29 is identical except that it employs method terminology). Claim 32 requires that “*the treatment lasts over a predetermined or randomly selected number of heart cycles*” (claim 32; claim 30 is identical except that it employs method terminology).

The wording of amended claim 15 and of new claims 29-32 is supported by the disclosure on pages 36-38 of the application as originally filed.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631; 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Thus, for anticipation the “identical invention must be shown in as complete detail as is contained in the ...

claim". *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236; 9 USPQ2d 1913, 1920 (Fed. Circ. 1989). MPEP §2131.

Since neither a microprocessor programmed in this way with specified patterns of treatment or a random number generator are provided in the prior art as required by claims 15 and 22, these claims 15 and 22, as well as dependent claims 29-32, are novel in their own right and not anticipated by Krikorian.

Dependent claims 17, 20, 21, 24, 27 and 28, which were also rejected for anticipation by Krikorian, are not anticipated by it since they depend from allowable parent claims.

The Section 103 Rejection

Alternatively, the same claims 15, 17, 20-22, 24 and 27-28 were rejected for obviousness over Krikorian because it was considered to be obvious to one of ordinary skill in the art to modify the method and apparatus of Krikorian with a time offset lying in a range from 5 % of the R-R length before the expected end of the T-wave up to 45 % of the R-R path length after the end of the T-wave, since it has been held that where the "general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art [citation omitted] and/or since it has been held that a *prima facie* case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties" (Office Action, page 4).

Independent apparatus and method claims 15 and 22, respectively, are not merely limited to the recited ranges. These claims are additionally limited as discussed above in connection with their Section 102 rejection, and in sum and substance recite, as stated above, that at least one of the stated parameters and offset are varied "in accordance with a predetermined pattern stored in the associated microprocessor or the random generator within pre-specified limits in the course of a treatment extending over many heart cycles". The Office Action did not address this limitation at all. As discussed in the Section 102 portion of this Amendment, these

limitations address the fundamental difference between the present invention and Krikorian as outlined above.

Indeed, Krikorian does not even recognize the problem of muscles becoming accustomed to stimulation applied to them (which can happen even with sequencing as discussed above).

As discussed above, in Krikorian the operator must choose specific values of the listed parameters which are retained for the treatment to which the patient is subjected. These parameters might be changed during treatment when the initially chosen parameter does not appear to be ideal for the particular treatment in question. Krikorian discloses to make individual adjustments if, upon observing the treatment, the chosen parameter does not appear optimal or ideal. In contrast, in the present invention as defined by the claims, and in particular independent claims 15 and 22, the parameters are varied in the course of treatment based on predetermined, stored patterns and not based on observation of the parameters generated during the treatment.

Krikorian contains no disclosure whatsoever to vary one or more of the parameters in accordance with a predetermined, stored pattern or randomly in accordance with a random number generator within pre-specified limits over the course of a treatment. One of ordinary skill in the art familiar with Krikorian would get no guidance from the reference whatsoever how to stimulate muscles in accordance with the present invention as recited in independent claims 15 and 22, as well as dependent claims 29-32. The knowledge and experience of the person of ordinary skill in the art would be of no assistance because the skilled person would have no knowledge or experience how to somehow modify Krikorian to arrive at the present invention as defined by the claims because there is no indication in Krikorian of the beneficial results obtained when stimulating muscles over an extended period and varying the stimulation in accordance with stored, pre-established patterns.

In view thereof, at least claims 15, 22 and 29-32 are not obvious over Krikorian.

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PATENT

The remaining dependent claims 2-21 and 23-28 are directed to specific features of the present invention which are independently patentable. These claims are further allowable because they depend from allowable parent claims.

CONCLUSION

In view of the foregoing, applicant submits that this application is in condition for allowance, and a formal notification to that effect at an early date is requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at (415) 273-4730 (direct dial).

Respectfully submitted,



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